

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference  CLJ/B45314	<b>FOR FURTHER ACTION</b> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No.  PCT/EP 03/08567	International filing date (day/month/year)  31/07/2003	(Earliest) Priority Date (day/month/year)  02/08/2002
Applicant  GLAXOSMITHKLINE BIOLOGICALS S.A.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 6 sheets.

It is also accompanied by a copy of each prior art document cited in this report.

**1. Basis of the report**

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
  - the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).
- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :
  - contained in the international application in written form.
  - filed together with the international application in computer readable form.
  - furnished subsequently to this Authority in written form.
  - furnished subsequently to this Authority in computer readable form.
  - the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
  - the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2.  **Certain claims were found unsearchable** (See Box I).

3.  **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

- the text is approved as submitted by the applicant.
- the text has been established by this Authority to read as follows:

VACCINE COMPOSITION COMPRISING TRANSFERRIN BINDING PROTEIN AND HSF FROM GRAM NEGATIVE BACTERIA

5. With regard to the **abstract**,

- the text is approved as submitted by the applicant.
- the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. \_\_\_\_\_

- as suggested by the applicant.
- because the applicant failed to suggest a figure.
- because this figure better characterizes the invention.

 None of the figures.

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP 03/08567

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K39/095 A61K39/102 A61K39/00

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, EMBASE, BIOSIS, MEDLINE

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>WO 01 09350 A (DALEMANS WILFRIED L J ;SMITHKLINE BEECHAM BIOLOG (BE); THIRY GEORG) 8 February 2001 (2001-02-08) cited in the application abstract page 12, line 32 -page 13, line 14 page 14, line 12 - line 22 page 20, line 11 - line 22 page 23, line 21 -page 24, line 7 page 25, line 11 -page 27, line 22 page 31, line 1 - line 22 page 31, line 30 -page 32 page 33, line 12 - line 30 page 36, line 11 - line 19 example 8 ---</p> <p style="text-align: center;">-/-</p>	20-25, 27-45, 51-63,65

 Further documents are listed in the continuation of box C. Patent family members are listed in annex.

## \* Special categories of cited documents :

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*8\* document member of the same patent family

Date of the actual completion of the international search

9 January 2004

Date of mailing of the international search report

20/01/2004

Name and mailing address of the ISA  
European Patent Office, P.B. 5818 Patentlaan 2  
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Noë, V

## INTERNATIONAL SEARCH REPORT

International Application No  
PCT/EP 03/08567

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 00 71725 A (PIZZA MARIAGRAZIA ;RAPPUOLI RINO (IT); CHIRON SPA (IT); GIULIANI M) 30 November 2000 (2000-11-30) cited in the application  abstract page 55, line 1-3 ---	1-8,13, 14, 16-19, 48-51, 55-59, 61,65
A	WO 00 25811 A (GORRINGE ANDREW RICHARD ;HUDSON MICHAEL JOHN (GB); MICROBIOLOGICAL) 11 May 2000 (2000-05-11) cited in the application abstract page 1, paragraph 1 page 3, last paragraph -page 4, paragraph 1 page 5, paragraph 4 -page 6, paragraph 1 page 6, paragraph 3 page 7, paragraph 5 -page 8, paragraph 1 claims 1,10-16,27,32 ---	
A	WO 99 31132 A (JENNINGS MICHAEL PAUL ;PEAK IAN RICHARD ANSELM (AU); UNIV QUEENSLA) 24 June 1999 (1999-06-24) cited in the application abstract page 34, line 10 -page 40, line 17 claims 1-11,20,21,29-33 ---	1-19, 48-52, 55-59, 66-71
A	WO 01 72337 A (GORRINGE ANDREW RICHARD ;HUDSON MICHAEL JOHN (GB); MICROBIOLOGICAL) 4 October 2001 (2001-10-04)  abstract page 5, line 14 - line 26 page 7, line 21 -page 8, line 10 page 10, line 6 - line 37 ---	1-3, 5-10,13, 14, 16-19, 46,47,64
A	MATHERS K ET AL: "ANTIBODY RESPONSE TO OUTER MEMBRANE PROTEINS OF MORAXELLA CATARRHALIS IN CHILDREN WITH OTITIS MEDIA" PEDIATRIC INFECTIOUS DISEASE JOURNAL, WILLIAMS & WILKINS, BALTIMORE, MD, US, vol. 18, no. 11, November 1999 (1999-11), pages 982-988, XP009003591 ISSN: 0891-3668 abstract -----	

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Present claims 1,20,21,26-32,35-43,45-48,51-56,58,60 relate to an extremely large number of possible immunogenic compositions and bacterial strains. Support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT is to be found, however, for only a very small proportion of the immunogenic compositions and bacterial strains claimed. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Consequently, the search has been carried out for those parts of the claims which appear to be supported and disclosed, namely those parts relating to the immunogenic compositions comprising proteins or outer membrane vesicles derived from *Neisseria*, *Moraxella catarrhalis* and *Haemophilus influenzae* (see examples and description page 12, last paragraph -page 14, paragraph 2).

Present claims 1-14, 16,18,20-43,45-48,51-71 relate to compounds defined by reference to a desirable characteristic or property, namely being a Hsf like protein or as defined in the description on page 9, line 3-4, sharing homology with Hsf of *Neisseria meningitidis*. The claims cover all compounds having this characteristic or property, whereas the application provides support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT for only a very limited number of such compounds. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Independent of the above reasoning, the claims also lack clarity (Article 6 PCT). Consequently, the search has been carried out for those parts of the claims which appear to be clear, supported and disclosed, namely those parts relating to the compounds disclosed in the description on page 9, line 11-25.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/EP 03/08567

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:  

Although claims 56,57,70 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2.  Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:  

see FURTHER INFORMATION sheet PCT/ISA/210
3.  Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1.  As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2.  As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3.  As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4.  No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
- No protest accompanied the payment of additional search fees.

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International Application No

PCT/EP 03/08567

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO 0109350	A 08-02-2001	AU 6833600 A BR 0012974 A CA 2380840 A1 CN 1377415 T CZ 20020403 A3 WO 0109350 A2 EP 1208214 A2 HU 0203056 A2 JP 2003506049 T NO 20020506 A TR 200200275 T2 TR 200202448 T2		19-02-2001 07-05-2002 08-02-2001 30-10-2002 15-05-2002 08-02-2001 29-05-2002 28-12-2002 18-02-2003 02-04-2002 21-05-2002 21-01-2003
WO 0071725	A 30-11-2000	AU 5097700 A BR 0010721 A CA 2373236 A1 CN 1362992 T EP 1179072 A2 WO 0071725 A2 JP 2003500420 T		12-12-2000 11-06-2002 30-11-2000 07-08-2002 13-02-2002 30-11-2000 07-01-2003
WO 0025811	A 11-05-2000	AT 242640 T AU 760858 B2 AU 1056900 A BR 9914946 A CA 2349331 A1 DE 69908805 D1 DK 1126874 T3 EP 1297844 A2 EP 1126874 A2 WO 0025811 A2 JP 2002528515 T US 2003215469 A1		15-06-2003 22-05-2003 22-05-2000 10-07-2001 11-05-2000 17-07-2003 29-09-2003 02-04-2003 29-08-2001 11-05-2000 03-09-2002 20-11-2003
WO 9931132	A 24-06-1999	AU 747742 B2 AU 1649599 A WO 9931132 A1 BR 9814276 A CA 2314319 A1 CN 1284965 T EP 1045859 A1 HU 0100094 A2 JP 2002508394 T NO 20002990 A NZ 505374 A PL 341160 A1 TR 200001709 T2 US 6495345 B1 US 2002102276 A1		23-05-2002 05-07-1999 24-06-1999 03-10-2000 24-06-1999 21-02-2001 25-10-2000 28-05-2001 19-03-2002 08-08-2000 01-03-2002 26-03-2001 21-03-2001 17-12-2002 01-08-2002
WO 0172337	A 04-10-2001	AU 4260201 A CA 2403993 A1 EP 1267938 A1 WO 0172337 A1 JP 2003528157 T US 2003082211 A1		08-10-2001 04-10-2001 02-01-2003 04-10-2001 24-09-2003 01-05-2003